

APPENDIX: Clean Copy of Claims as Amended

Sub 21
1. (amended) An isolated or purified nucleic acid segment comprising a nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein, wherein the nucleic acid sequence is selected from the group consisting of:

hi
a nucleic acid sequence at least about 80% identical to SEQ ID NO:8 which hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof; and

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9 which is immunoreactive with an antibody immunoreactive with SEQ ID NO:9

Sub 22
3. A recombinant vector comprising in the 5' to 3' direction:

a) a promoter that directs transcription of a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein;

b) a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein; wherein the structural nucleic acid sequence is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:8;

a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof;

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9; and

a nucleic acid sequence encoding a protein that is immunoreactive with an antibody

prepared using SEQ ID NO:9 as an antigen, the antibody being immunoreactive with SEQ ID NO:9; and

c) a 3' transcription terminator.

4. A recombinant cell comprising a nucleic acid segment encoding a 3-keto-acyl-CoA reductase protein, wherein the nucleic acid segment is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:8;

a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof;

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9;

and

a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:9 as an antigen, the antibody being immunoreactive with SEQ ID NO:9.

5. A genetically transformed plant cell comprising in the 5' to 3' direction:

a) a promoter that directs transcription of a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein;

b) a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein; wherein the structural nucleic acid sequence is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:8;

Sub C2) a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof;

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9;
and

a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:9 as an antigen, the antibody being immunoreactive with SEQ ID NO:9;

c) a 3' transcription terminator; and
d) a 3' polyadenylation signal sequence that directs the addition of polyadenylate nucleotides to the 3' end of RNA transcribed from the structural nucleic acid sequence.

6. A genetically transformed plant comprising in the 5' to 3' direction:

a) a promoter that directs transcription of a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein;
b) a structural nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein;
wherein the structural nucleic acid sequence is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:8;
a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof;
a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9;

and

a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:9 as an antigen, the antibody being immunoreactive with SEQ ID NO:9;

c) a 3' transcription terminator; and

d) a 3' polyadenylation signal sequence that directs the addition of polyadenylate nucleotides to the 3' end of RNA transcribed from the structural nucleic acid sequence.

Sub C3
9. An isolated or purified nucleic acid segment comprising a nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein, wherein the nucleic acid segment is selected from the group consisting of:

h
a nucleic acid sequence at least about 80% identical to SEQ ID NO:10 which hybridizes under stringent conditions to SEQ ID NO:10 or the complement thereof; and

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11 which is immunoreactive with an antibody immunoreactive with SEQ ID NO:11.

Sub C4
11. A recombinant vector comprising in the 5' to 3' direction:

a) a promoter that directs transcription of a structural nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein;

b) a structural nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein; wherein the structural nucleic acid sequence is selected from the group consisting of:

- c4
- a nucleic acid sequence at least about 80% identical to SEQ ID NO:10;
 - a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:10 or the complement thereof;
 - a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11; and
 - a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:11 as an antigen, the antibody being immunoreactive with SEQ ID NO:11; and
- c) a 3' transcription terminator.

12. A recombinant host cell comprising a nucleic acid segment encoding a polyhydroxyalkanoate synthase protein, wherein the nucleic acid segment is selected from the group consisting of:

- a nucleic acid sequence at least about 80% identical to SEQ ID NO:10;
- a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:10 or the complement thereof;
- a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11; and
- a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:11 as an antigen, the antibody being immunoreactive with SEQ ID

NO:11.

13. A genetically transformed plant cell comprising in the 5' to 3' direction:

- c4
- a) a promoter that directs transcription of a structural nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein;
 - b) a structural nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein; wherein the structural nucleic acid sequence is selected from the group consisting of:
 - a nucleic acid sequence at least about 80% identical to SEQ ID NO:10;
 - a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:10 or the complement thereof;
 - a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11; and
 - a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:11 as an antigen, the antibody being immunoreactive with SEQ ID NO:11;
 - c) a 3' transcription terminator; and
 - d) a 3' polyadenylation signal sequence that directs the addition of polyadenylate nucleotides to the 3' end of RNA transcribed from the structural nucleic acid sequence.

14. A genetically transformed plant comprising in the 5' to 3' direction:

- a) a promoter that directs transcription of a structural nucleic acid sequence

CU > encoding a polyhydroxyalkanoate synthase protein;

- b) a structural nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein; wherein the structural nucleic acid sequence is selected from the group consisting of:
- a nucleic acid sequence at least about 80% identical to SEQ ID NO:10;
 - a nucleic acid sequence that hybridizes under stringent conditions to SEQ ID NO:10 or the complement thereof;
 - a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11; and
 - a nucleic acid sequence encoding a protein that is immunoreactive with an antibody prepared using SEQ ID NO:11 as an antigen, the antibody being immunoreactive with SEQ ID NO:11;
- c) a 3' transcription terminator; and
- d) a 3' polyadenylation signal sequence that directs the addition of polyadenylate nucleotides to the 3' end of RNA transcribed from the structural nucleic acid sequence.

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additional fee be required, the Commissioner is hereby authorized to charge the fee to Deposit Account No. 50-1868.

In the Claims

1. (amended) [A]An isolated or purified nucleic acid segment comprising a nucleic acid sequence encoding a 3-keto-acyl-CoA reductase protein, wherein the nucleic acid sequence is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:8[;] which

[a nucleic acid sequence that]hybridizes under stringent conditions to SEQ ID NO:8 or the complement thereof; and

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:9[; and] which

[a nucleic acid sequence encoding a protein that] is immunoreactive with an antibody [prepared using SEQ ID NO:9 as an antigen, the antibody being] immunoreactive with SEQ ID NO:9.

9. [A]An isolated or purified nucleic acid segment comprising a nucleic acid sequence encoding a polyhydroxyalkanoate synthase protein, wherein the nucleic acid segment is selected from the group consisting of:

a nucleic acid sequence at least about 80% identical to SEQ ID NO:10[;] which

[a nucleic acid sequence that] hybridizes under stringent conditions to SEQ ID NO:10 or

the complement thereof; and

a nucleic acid sequence encoding a protein at least about 80% identical to SEQ ID NO:11[; and] which

[a nucleic acid sequence encoding a protein that]is immunoreactive with an antibody [prepared using SEQ ID NO:11 as an antigen, the antibody being] immunoreactive with SEQ ID NO:11.

Remarks

Amendment to the claims

Claims 1, 3-6, 9, and 11-14 were rejected. Claims 1 and 9 were amended as discussed below. Support is found at least in the original claims and at p. 11, line 5; p. 27, lines 25, 27-29; p. 33, lines 5-6 and 16-20.

Rejection under 35 U.S.C. § 101

Claims 1 and 9 were rejected as drawn to a product of nature. Claims 1 and 9 have been amended to recite "an isolated or purified" nucleic acid segment as suggested by the Examiner.

Rejection under 35 U.S.C. § 112

Claims 1, 3-6, 9 and 11-14 were rejected for allegedly lacking sufficient description under 35 U.S.C. § 112, first paragraph. The applicants respectfully disagree.

The proper standard in evaluating whether the written description requirement has been satisfied is whether the description conveys with reasonable clarity to those skilled in the art that,

as of the filing date sought, the inventor was in possession of the invention (see, i.e. Fujikawa v. Wattanasin, 93 F.3d 1559, 1570, 39 USPQ2d 1895, 1904 (Fed. Cir. 1996)).

In holding that the claimed subject matter lack sufficient description, the Examiner essentially concluded that the description of a gene with "at least about 80%" homology to the gene SEQ ID NO: 8 and SEQ ID NO: 10 does not convey to one of ordinary skill in the art with reasonable clarity what the claimed subject matter is because allegedly there is disclosure of common elements among the claimed sequences. The applicants respectfully disagree. It has been a common practice in the art of gene engineering to describe a genus of gene sequence in terms of certain percentage of a known gene sequence (see, for example, Schubert et al., "Molecular analysis of the *Alcaligenes eutrophus* poly(3-hydroxybutyrate) biosynthetic operon: identification of the N terminus of poly(3-hydroxybutyrate) synthase and identification of the promoter" in *J Bacteriol* 173(1):168-175 (1991); Vieille et al., "Characterization of an *Azospirillum brasilense* Sp7 gene homologous to *Alcaligenes eutrophus* phbB and to *Rhizobium meliloti* nodG" in *Mol Gen Genet* 231(3):375-384 (1992); and Pries, et al., "Identification and characterization of two *Alcaligenes eutrophus* gene loci relevant to the poly(beta-hydroxybutyric acid)-leaky phenotype which exhibit homology to ptsH and ptsI of *Escherichia coli*" in *J. Bacteriol* 173(18):5843-5853 (1991)). It is also within the knowledge in the art to select proteins having a potentially desirable function by identifying proteins encoded by a nucleic acid sequence which has a certain degree of homology to a known sequence of nucleic acids encoding

a protein with a known function (see, for example, Barrett, et al., "The MEROPS Database as a Protease Information System" in J Struct Biol. 134(2/3):95-102 (2001)).

The claimed subject matter requires that there be a nucleic acid sequence which is at least about 80% identical to SEQ ID NO: 8 encoding a 3-ketoacyl-CoA reductase protein or at least about 80% identical to SEQ ID NO: 10 encoding a polyhydroxyalkanoate synthase protein. One of ordinary skill in the art can identify whether a sequence encodes a 3-ketoacyl-CoA reductase protein or a PHA synthase protein. Moreover, one of ordinary skill in the art can readily determine the homology of a sequence to SEQ ID NO: 8 or SEQ ID NO: 10 by an automatic means such as computerized calculation or computation (see Barrett, supra). The specification at p. 67, line 3 to p. 69, line 15, further teaches one of ordinary skill in the art the methods for the determination of homologous and degenerate nucleic acid sequences of the disclosed sequences. Therefore, the specification conveys to one of ordinary skill in the art with reasonable clarity the claimed subject matter (see Fujikawa, 93 F.3d at 1570, 39 USPQ2d at 1904).

The Examiner further alleged that the specification lacks sufficient disclosure because "no written description of introns, of upstream or downstream regions containing promoters and enhancers, or of alternative splice variants has been disclosed." The applicants respectfully direct the Examiner's attention to p. 55, line 10 to p. 56, line 23 where various 5' upstream region putative promoters have been disclosed as examples and p. 70, line 8 to p. 71, line 14 where various 5' regulatory region plant promoters have been disclosed as examples. As for introns


and/or alternative splice variants, one of ordinary skill in the art would know that they are not critical to the function of the disclosed nucleic acid sequence. The specification does disclose that the sequence can include additional sequences in genomic fragment (p. 63, lines 7-16).

The Examiner further alleged that the specification lacks description of hybridization. The applicants respectfully direct the Examiner to p. 65, line 3 to p. 67, line 2, Example 18, where the applicants disclosed as examples the various modes of nucleic acid sequence hybridization.

In sum, the specification contains sufficient description of the claimed subject matter.

Allowance of all claims 1, 3-6, 9, and 11-14, as amended, is earnestly solicited.

Respectfully submitted,



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